

## SPRAY DRY COACERVATION SYSTEMS AND METHODS

### ABSTRACT OF THE DISCLOSURE

Microparticle formation system and methods that advantageously combine aspects of spray drying and coacervation (or complex coacervation) into a single process. A temperature controllable spray head mounted on a movable stage within a spray chamber produces droplets of solution having controlled size and temperature. The solution can include a first set of one or more solvents and a first set of one or more components or active agents such as one or more APIs. A wet sample receiving pan or reservoir at the bottom of the chamber holds a desired receiving solvent or solvents. The droplets traverse the path between the spray head and reservoir and interact with the solvent in the reservoir. As the droplets traverse the path the first solvent dries. However, the system is configurable such that the first solvent of the droplets does not have to fully dry before the droplets reach the reservoir. This provides flexibility to perform a second process using the reservoir solvent(s) to refine the sprayed droplets, for example to produce microparticles having certain properties unmet by other processes or techniques. The first solvent may be miscible with a reservoir solvent such that coacervation occurs resulting in formation of one or more microparticles of the first set of components or active agents (or a subset thereof). Microparticles formed in this manner have a well-defined or controlled size of low polydispersity not previously available using other techniques. The size and other properties of the formed microparticles, such as integrity and stability, are determined, in part, by the concentration of solution in the droplets. Advantageously, the present invention therefore greatly enhances the capability of spray drying by allowing for the control of several process parameters. For example, four primary process parameters are spray head temperature, flow rate, temperature gradient along the path of the sprayed droplet and the solvent(s) in the reservoir. Other parameters such as pressure can be controlled as well. The process allows for droplets of controlled size and concentration to be provided to the reservoir for further processing, such as coacervation.